

### REMARKS

This is in response to the non-final Official Action of January 6, 2009. Claims 1-5 are pending the application and stand rejected as anticipated by Orlowski (CA 2,001,688). Without conceding the rejection, Applicants submit herewith amendments to the claims to more clearly point out and distinctly claim various embodiments of Applicants' invention. It is respectfully submitted that these amendments obviate the rejection.

Claim 1 has been amended to recite that the composition is a pharmaceutical composition and that it "consists essentially of" a bioactive agent and Gilsonite oil. By resort to that transitional phrase, and in keeping with U.S. practice and jurisprudence, the scope of the claim is limited to pharmaceutical compositions wherein the only components substantively affecting the results and effectiveness of the composition are the bioactive agent and Gilsonite oil. Thus, extraneous components such as mineral oil would be excluded, as would other components of the Gilsonite ore. Support for a composition containing only a bioactive agent and Gilsonite oil is found within the specification at page 5, paragraph 0015.

Additionally, Applicants have added new claims 37-40. Applicants submit that those claims are directed to the same patentable invention as appears in claim 1. Accordingly, further examination of these claims is appropriate and respectfully requested.

Claim 37 is directed to a formulation wherein the Gilsonite oil is present in specified quantities, and has a viscosity of about 5 to about 1,000 cps at 25°C and a specific gravity of about 0.8 to about 0.95. Additional claims are directed to pharmaceutical compositions wherein the Gilsonite oil has a viscosity of about 5 to

about 100 cps. Support for these Gilsonite oils and their concentration within the pharmaceutical compositions of the instant claims is found within the specification, e.g., at page 12, paragraph 0042, and at pages 5-6, paragraph 0016.

The Orlowski reference does not teach or suggest the use of a Gilsonite oil. Rather, and as argued previously, the Orlowski reference describes a suspension of raw Gilsonite ore in mineral oil in combination with other ingredients. Nothing within the Orlowski reference teaches or suggests the existence or the use of Gilsonite oil, per se. Further, nothing in that reference teaches or suggests the particular Gilsonite oil claimed here, nor does it teach or suggest the claimed ranges of Gilsonite oil in the pharmaceutical compositions.

The second Declaration of Gary Fisher submitted herewith demonstrates that the Gilsonite oil of instant claim 37 and its dependent claims is present in Gilsonite ore in concentrations of only about 0.1 weight percent. Orlowski uses Gilsonite ore suspended in mineral oil. Thus, it would not be possible for the Orlowski formulation to have even 0.1 weight percent Gilsonite oil, much less an amount substantially greater than that. The instant claim 37 and its dependent claims recites a pharmaceutical composition having a Gilsonite oil concentration of about 1 to about 80 weight percent. Alternatively, the claims recite a more narrow weight percent range of the Gilsonite oil and/or a Gilsonite oil of a more narrow range of viscosity. As constituted, it would not be possible for the Orlowski composition to have the specified concentration of Gilsonite oil, and particularly of the Gilsonite oil specified. Accordingly, the Orlowski reference does not anticipate nor does it render obvious, the claimed invention.

The claims require a composition comprising nicotine, caffeine, or hydrocortisone. The Official Action acknowledges that Orlowski does not teach or suggest such compositions comprising hydrocortisone. It is asserted that US '392 teaches the use of hydrocortisone in nail treating compositions. However, this fails to cure the deficiencies of Orlowski, particularly in light of the present amendments. Notably, US '392 fails to teach or suggest compositions comprising Gilsonite oil of the specified composition in the specified concentration ranges. Accordingly, neither Orlowski nor US '392, taken alone or together, teach or suggest the presently claimed invention.

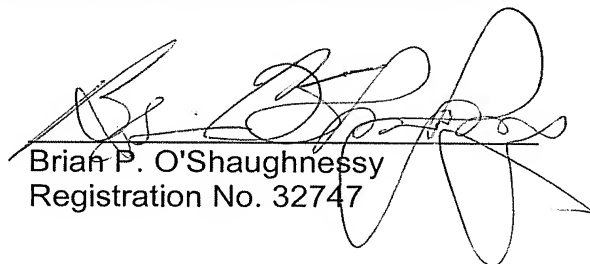
In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

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